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Supplementary Material

Article Title: Response and Safety Outcomes in Treatment-Resistant Depression After Subcallosal Cingulate Gyrus Deep Brain Stimulation: Long-term Follow-up Study

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APPENDIX 1

Supplementary Material. Long-term management and safety

Suicide commitment: Two patients with BPD committed suicide long time after surgery. In one of these two cases, suicide occurred during a depressive relapse. This patient, diagnosed with a BPD and a very chronic and refractory index depressive episode (more than 10 years), responded to DBS for up to 6 months, even achieving remission criteria. Nevertheless, this participant had to be considered as part of the NR/NR group, because symptom amelioration occurred at the borderline of the first and second year after SCG-DBS, and the final improvement according to the IDI-HAM-D_{17} scores was less than 50% in either of these years. Afterwards and undertreated with mood stabilizers, she experienced a manic episode for which the professionals conveyed in turning off the IPG as a precautionary measure. Soon after she suffered a depressive relapse, was hospitalized for 5 months and SCG-DBS was gradually re-started up to 3V. Given the symptomatic severity, she also received 10 ECT sessions with good response (but not remission). Two months after discharge and being in a fragile stability, she committed suicide. In the second case, suicide occurred 7 years after the intervention, when there had been a gradual sustained response without functional recovery. Here, the suicide also occurred in close proximity to a manic episode in a patient with a BD but this time in the absence of a subsequent depressive shift, and surrounded by environmental stressors although in circumstances that could not be fully clarified. This case was unrelated to DBS hardware dysfunction or recent parameter changes.

ECT: Five patients received ECT at least once after SCG-DBS. Before surgery, all of them had previously been on maintenance ECT without sufficient response and/or with unbearable cognitive problems. After intervention, ECT was indicated because of the severity of depressive symptoms (in some cases associated with intense suicidal ideation) in those patients who had shown no response to SCG-DBS yet (n=3, in whom a change of parameters or electrode repositioning was subsequently considered) or in patients who experienced a severe recurrence months or even several years after achieving

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sustained remission with SCG-DBS (n=2; one of whom in up to 4 episodes, one shortly after DBS implantation and two shortly after rechargeable battery had been depleted, mainly following delirium with pre-existing cognitive impairment and infections). Bifrontal ECT was administered in variable series of 6-12 sessions at a frequency of 2-3 sessions per week; in one case, ECT has been maintained for 5 years at an average rate of 1 session/week due to poor response to SCG-DBS (311 sessions so far). DBS devices were turned off prior to ECT courses or immediately before each session, turning them back on. ECT was effective in all cases (even in patients in whom it had ceased to be efficacious prior to SCG-DBS) without any unexpected adverse effect to the patients or to the DBS hardware. Only low impedances between two ipsilateral contacts were found in the IPG of the patient on maintenance ECT, suggesting a potential short-circuit; nevertheless, the remaining impedances were within normal range not affecting current therapeutic stimulation.

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Supplementary Table 1. Adverse events in patients receiving deep brain stimulation of the subcallosal cingulate gyrus for treatment-resistant depression (TRD). DBS= deep brain stimulation; IPG= impulse generator.

Adverse Events	Number of events
Non-psychiatric	78
DBS IPG replacement due to system failure	1
DBS reimplantation to improve targeting	1
Infection related to DBS system	0
DBS accidentally disconnected in non-rechargeable IPG	8 (involving 4 patients), 4 of which associated with serious worsening/relapses
DBS disconnected in rechargeable IPG	15 (involving 6 patients)
Rash	2
Subdural hematoma after mild traumatic brain injury (3 years after DBS)	1
Spinal arachnoid cyst	1
Senile cognitive impairment	1
Neuroleptic-induced movement disorders	3 (involving 3 patients)
Focal epileptic seizures (7 years after DBS)	1
Restless legs syndrome	1
Headache	4
Mild renal insufficiency	1
Urinary tract infection	20 (18 of which in 1 patient)
Gastrointestinal	3 (involving 2 patient)
Eyelid oedema/cellulitis/ptosis	3 (involving 3 patients)
Pulmonary embolism	1
Deep venous thrombosis	4 (involving 1 patient)
Iron-deficiency anaemia	3 (involving 2 patients)
Gynaecologic	2 (involving 2 patients)
Subclinical hypothyroidism induced by lithium salts	1
Meniscal injury	1
Death (non-suicide)	1
Psychiatric	44
Suicidal ideation	5
Suicide attempt	7 (involving 5 patients)
Suicide commitment	2
Auditory hallucinations	1
Relapse into cocaine use	1
Mania/hypomania	6 (involving 5 patients)
Serious depression worsening/recurrences	21 (16 involving 2 patients)
Total	122
Surgery-related	1
Device-related	24

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